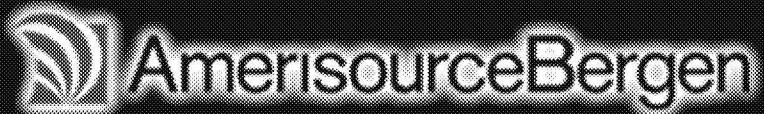


# **EXHIBIT 19**



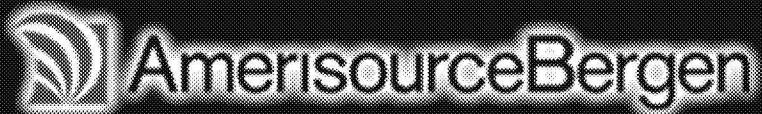
# **Drug Enforcement Administration Pharmaceutical Industry Conference**

## **Wholesale Distribution Diversion Control Program**

**September 11, 2007**

**Chris Zimmerman  
Vice President - Corporate Security & Regulatory Affairs  
AmerisourceBergen Corporation**

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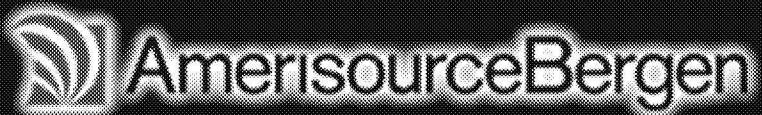


## Regulatory Responsibility

Title 21 of the Code of Federal Regulations:

**1301.71(a)** - "All applicants and registrants shall provide **effective controls** and procedures to **guard against** theft and **diversion** of controlled substances."

Distributor Response: Develop policy to ....



## HOW?

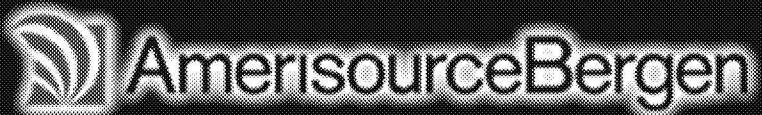
Distributors usually implement policies that mirror the Code of Federal Regulations' requirements:

**1301.72 - Physical Security Controls** – vault / cage construction and alarm system requirements – No Problem

**1304 – Records and Reports of Registrants** – information, maintenance, and inventory requirements – No Problem

**1305 – Orders For Schedule I & II Controlled Substances** – ordering, filling, executing, and endorsing DEA Forms 222 – No Problem

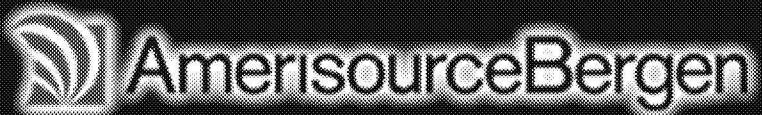
**1301.74 – Other Security Controls** – make a **good faith** inquiry; report suspicious orders; report **significant** losses – gray area



## Regulatory Responsibility

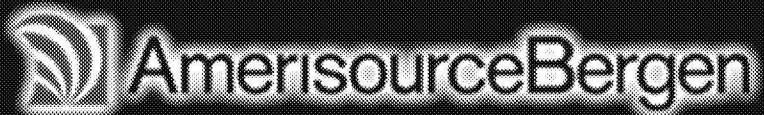
Title 21 of the Code of Federal Regulations:

**1301.74(b)** - "The registrant shall design and operate a system to disclose to the registrant **suspicious orders** of controlled substances. The registrant shall inform Field Diversion Office of the Administration in his area of suspicious orders **when discovered** by the registrant."



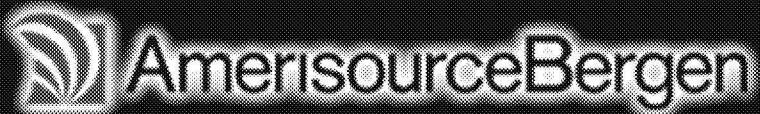
## Regulatory Responsibility

- ▶ Reporting suspicious orders to DEA does NOT relieve the distributor of the responsibility to maintain effective controls to prevent diversion.
- ▶ DEA cannot / will not tell a distributor:
  - if an order is or is not legitimate; and/or
  - if the distributor should or should not ship an order
- ▶ Distributor must make a “business” decision whether or not to ship the order.



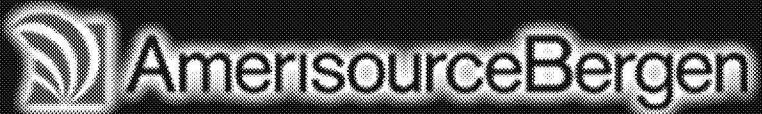
# ABC's Diversion Control Program

- ▶ **“Know Your Customer” Due Diligence**
- ▶ **Order Monitoring Program (OMP)**
- ▶ **Investigations**
- ▶ **Education and Training**



## New Customer Due Diligence

- ▶ “Know Your Customer” Due Diligence investigations completed on all new Retail and Wholesale Accounts.
  - Retail chain pharmacies are exempted.
- ▶ Included in New Account Setup Process
  - New Account Questionnaire
  - On-site visit includes photographs inside and out (or physical description of premises)



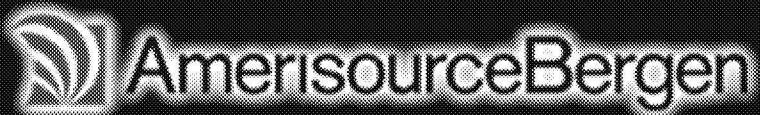
## New Customer Due Diligence

- ▶ Monthly Sales Limits
  - All new accounts set at the lowest threshold level for DEA business type in ABC's Order Monitoring Program (OMP)
- ▶ “Do Not Ship” List
  - Customers to whom ABC has ceased distribution to due to suspicious activity
  - Other sources



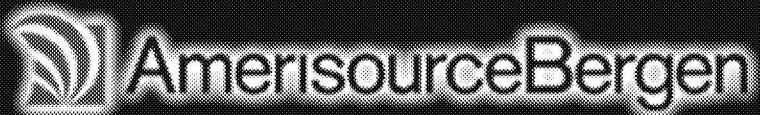
## Order Monitoring Program (OMP)

- ▶ The Controlled Substances/Listed Chemicals Order Monitoring Program (OMP) was developed to identify suspicious orders and purchasing trends.
- ▶ Historically Controlled Substance / Listed Chemical order monitoring has been based on a **ship and report** process.
- ▶ ABC's OMP process is now based on: identify, capture, investigate, and report suspicious orders; all **prior to shipment**.



## OMP Customer Account Type and Size

- ▶ Each Customer is classified by “Customer Type,” which represents how the customer is registered with DEA.
  - Hospital/Clinic, Retail Pharmacy, Distributor, etc.
  - This value is loaded using the NTIS Database synch process.
  
- ▶ Each customer is then categorized by “Customer Size” based upon average revenue relative to its peers in the same “Customer Type.”



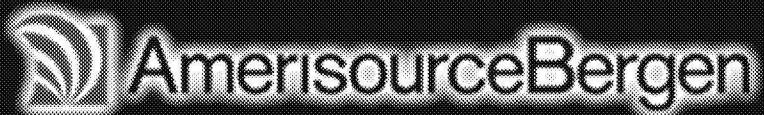
## OMP Item Family and Threshold

- ▶ All controlled substance and listed chemical products are grouped into item “families” based upon the drug’s active ingredient, which has a corresponding Generic Code Number (GCN).
  
- ▶ The OMP will combine all sales of items within the same GCN family (e.g., hydrocodone / vicodin; oxycodone / percocet; Alprazolam / Xanax), for each customer.



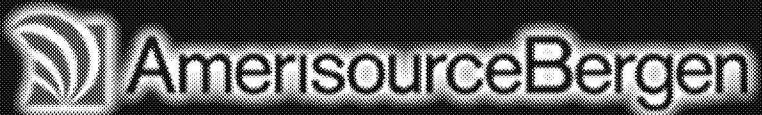
## OMP Item Family and Threshold

- ▶ Item threshold levels are established from accumulated monthly sales for all customers based on item family, DEA type, and customer size.
  
- ▶ A customer's threshold level is initially set by item family based on the customer's DEA type and customer size.



## OMP Order Processing

- ▶ A customer's incoming orders are accumulated by item family, and the total item family order quantity is applied to the predetermined Item family monthly threshold.
  
- ▶ If the order quantity falls below the Item family threshold, the order will process normally.



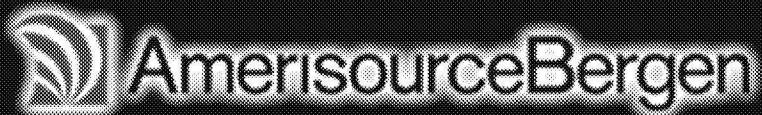
## OMP Order Processing

- ▶ If the order quantity goes over the item family threshold, the order will be placed into “OMP Review.”
- ▶ All subsequent orders within the same item family will be rejected while an item within the same family is under review.
- ▶ Each distribution center (DC) is responsible for initial review of all orders in OMP Review.
  - If the DC can determine the order is not suspicious, the DC will release the order.
  - If the DC is unsure, the order will be flagged to be investigated by Corporate (CSRA).



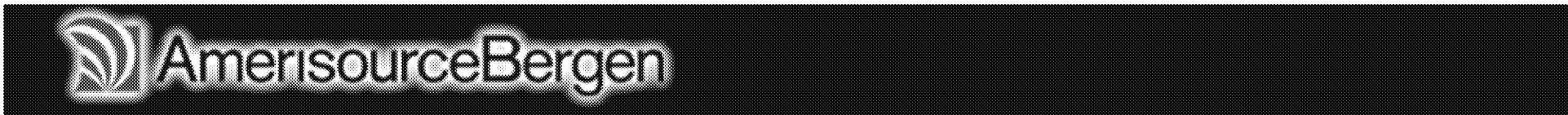
## OMP Order Processing

- ▶ All OMP orders that the DC released, as well as those flagged for CSRA Review, are sent to CSRA each morning.
- ▶ Based upon information available to CSRA, flagged orders will either be released or placed in “Investigate” status.
- ▶ All orders placed into Investigate status are electronically reported to DEA on a daily basis.

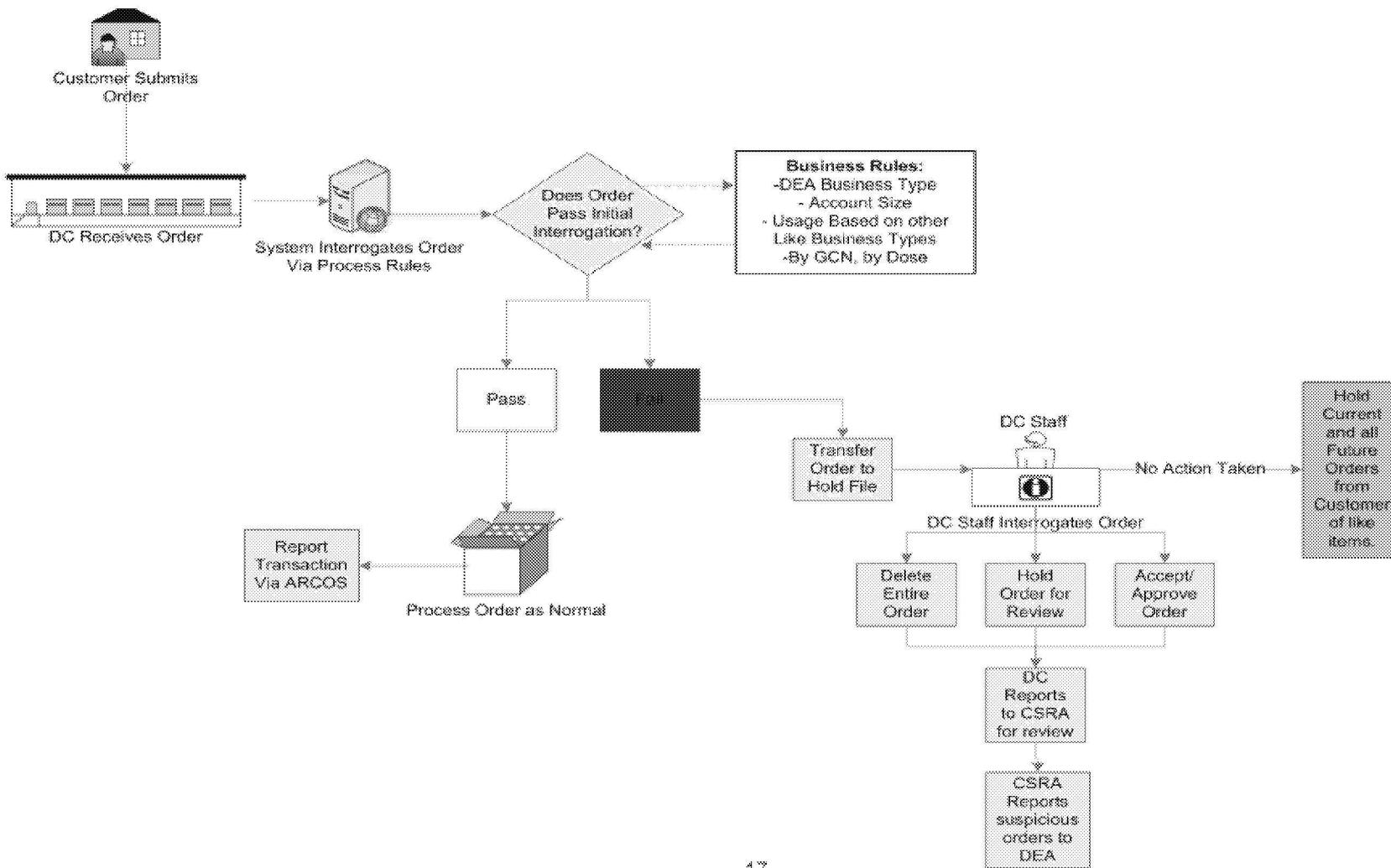


## OMP Order Processing

- ▶ CSRA conducts the investigation and will notify the distribution center of the final disposition of the order (release or cancel).
- ▶ CSRA will also determine if any permanent action needs to be taken with the customer.
  - Customers who have legitimate needs will have their size or threshold levels increased.
  - Customers with continued suspicious ordering patterns may have their ability to order control substances effected.

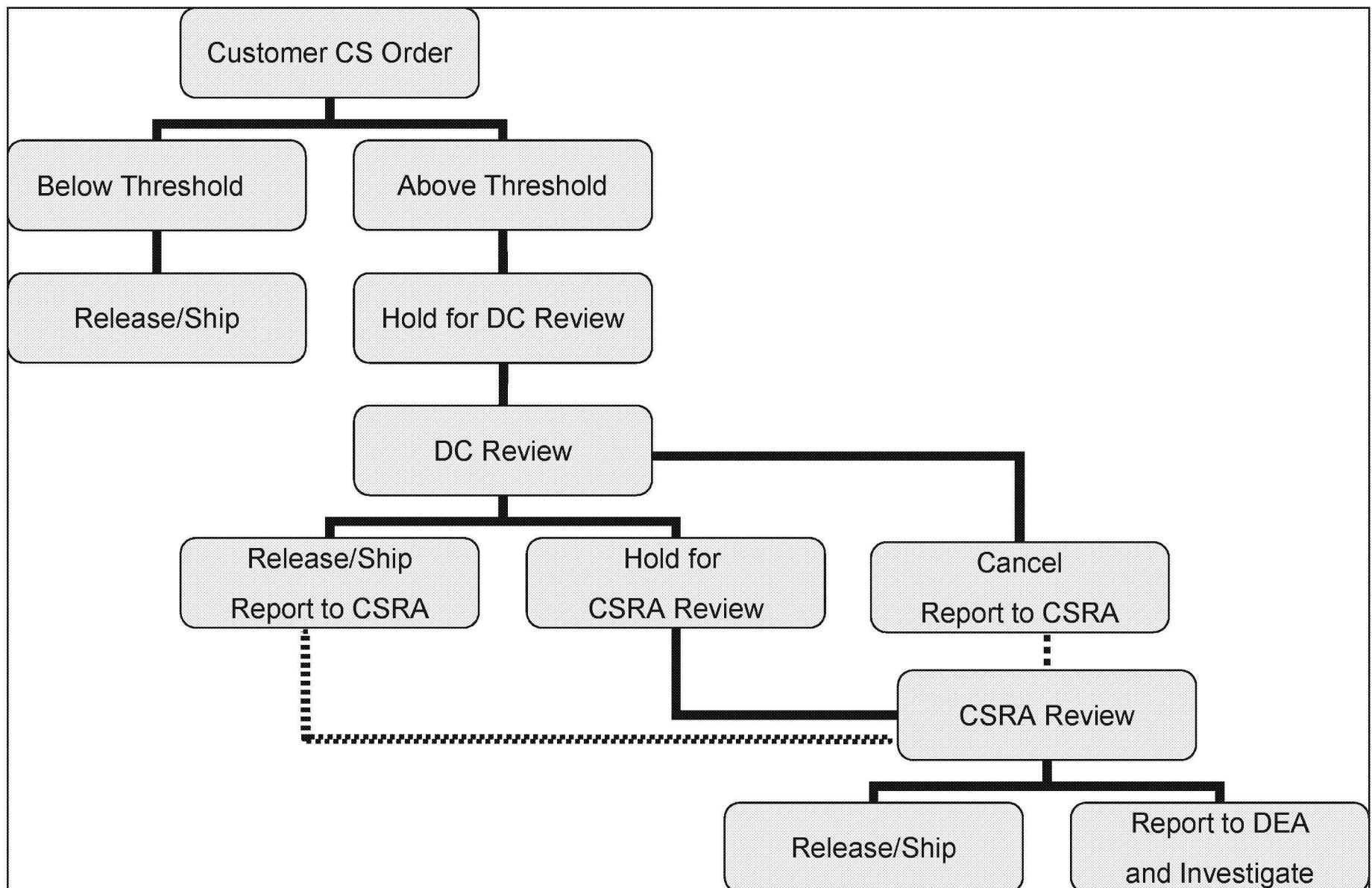


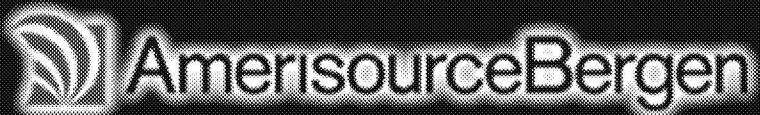
## Order Monitoring Process (OMP)



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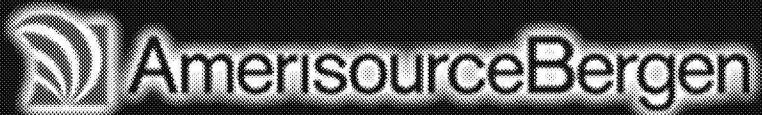
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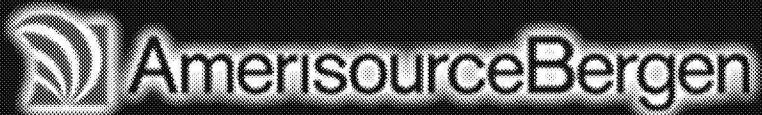
## Order Monitoring Program (OMP)

- ▶ A Distributor can't solely rely on computer systems and programs to prevent diversion.
- ▶ All employees have a role and responsibility in a successful Order Monitoring Program:
  - Sales
  - Procurement
  - Management (DC / HQ)
  - Order fillers
  - Customer service
  - IT



# Investigations

- ▶ Sources of Investigations
  - Order Monitoring Program (OMP)
  - Monthly Customer Product Mix Report
  - Notification by DEA
  - Notification by ABC DC
- ▶ Typical Investigation Process
  - One-year purchase history
  - On-site inspection
  - **CSRA Form 590c Retail Pharmacy Verification Checklist**
- ▶ Decision
  - Cease distribution of CS/LC to customer
  - Customer Sign applicable compliance agreement



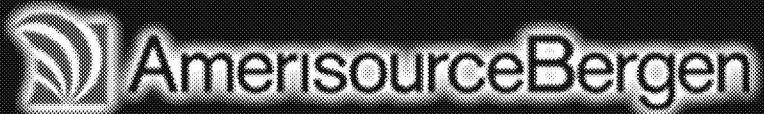
## Education and Training

- ▶ All appropriate associates are trained on ABC's Diversion Control Program
- ▶ ABC also holds training and educational courses for its customers and vendors regarding this subject matter.



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# Questions?

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